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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1630]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" (VICH GL22); Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry (#115) entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies'' (VICH GL22). This draft guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). This draft VICH guidance document recommends a basic battery of tests that can be used to evaluate the reproduction safety of veterinary drug residues in human food.

DATES: Submit written comments concerning the draft guidance to ensure their adequate consideration in preparation of the final document by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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Identify comments with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

Copies of the draft guidance entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies'' (VICH GL22) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/fda/TOCs/guideline.html. Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

Regarding VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail: sthompso@cvm.fda.gov, or Carole R. Andres, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6524, e-mail: candres1@cvm.fda.gov.

Regarding the guidance document: Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: lmulliga@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical requirements for drug development among regulatory agencies.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the: European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Reproduction Studies

The VICH Steering Committee held a meeting on June 14 through 16, 2000, and agreed that the draft guidance entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies'' (VICH GL22) should be made available for public comment.

This draft guidance is intended to provide harmonized guidance on the core recommendation for a multigeneration study for the safety evaluation of veterinary drug residues in human food. The current draft guidance is one of a series of guidances developed to facilitate the mutual acceptance of safety data necessary for the determination of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the safety evaluation of veterinary residues in human food (VICH Guidance on General

Testing Approach) will be made available at a later time. VICH GL22 was developed after consideration of the existing ICH guidance for pharmaceuticals for human use on ''Detection of Toxicity to Reproduction for Medicinal Products'' and its addendum, ''Toxicity to Male Fertility,'' in conjunction with the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, the United States, Australia, and New Zealand. (Information collection is covered under OMB Control Nos. 0910–0117 and 0910–0032).

III. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). For example, the documents have been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH documents have been substituted with ''should.'' Similarly, words such as ''requirement'' or ''acceptable'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context.

This draft guidance represents the agency's current thinking on reproduction safety studies for veterinary drug residues in human food. This draft guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations. Comments about the draft guidance documents will be considered by FDA and the VICH Safety Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidances and publish them as future guidances.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Submit written comments to ensure

adequate consideration in preparation of the final guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 12/7/00
December 7, 2000.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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